VISIA Results – Reduction in Red Areas

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Tradename: AC ExoCalm

Code: 60192

CAS #: 7732-18-5 & 84775-66-6 & 123465-35-0 (or) 8002-43-5

Test Request Form #: 10116

Lot #: N230517B

Sponsor: *Active Concepts, LLC; 107 Technology Drive Lincolnton, NC 28092*
Study Director: *Maureen Drumwright*
Principle Investigator: *Kayla Patterson*

Test Performed:
In-vivo VISIA Analysis

Introduction
Red areas represent a variety of skin conditions such as acne, inflammation, rosacea, or spider veins. These structures get their red color from blood vessels and hemoglobin that are contained in the papillary dermis. Reducing red areas leads to a more youthful and healthy skin appearance.

An *in-vivo* study was conducted over a period of six weeks to evaluate the effects of 3.0% **AC ExoCalm** in a base lotion on red area parameters compared to the base lotion alone.

Assay Principle
Photographic assessments were performed using the VISIA Complexion Analysis System (Canfield Scientific., Fairfield, NJ, USA). The VISIA System, with a configurable head support, ensured consistent positioning of each subject's head. The subjects cleaned their skin with a gentle facial wipe (Simple® Cleansing Facial Wipes) before the image was obtained. The photographic images were captured with standard, cross-polarized, parallel polarized, and ultraviolet light. Baseline photos were taken prior to starting the lotion regimen. Photos were taken once a week during the four-week use period and for two weeks after application ceased for a total of six weeks. Female participants were instructed to not wear makeup during the testing period.

Materials
A. Equipment: VISIA Complexion Analysis System (Canfield Scientific., Fairfield, NJ, USA)

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Methods

This study was conducted using 10 M/F participants between the ages of 23 – 40 with Fitzpatrick skin types of I to IV (Table 1). Each participant was instructed to apply 2.0 mg of lotion to their entire face twice a day for a four-week period. Participants were instructed to continue their usual skin care routine and to apply the lotion once their everyday skin care routine is finished. Half of the participant population used 3.0% **AC ExoCalm** in a Simple® Hydrating Light Moisturizer for all skin types, while the other half used the Simple® Hydrating Light Moisturizer alone as a control.

Images were analyzed for Red Area Feature Counts. The Red Area Feature Counts indicate the number of discrete instances of Red Areas within the analyzed region. Skin with lower counts is considered to be more youthful in appearance.

For added perspective, skin age was determined using the VISIA Complexion Analysis System.

Table 1. The Fitzpatrick Classification of Skin Types Chart[1]

Fitzpatrick Skin Type Descriptions*	
Skin Type	**Description**
I	Always burns, never tans
II	Burns easily, tans minimally
III	Burns moderately, tans to light brown
IV	Burns minimally, tans to moderate brown
V	Rarely burns, tans to dark
VI	Never burns, least sensitive to changes
*Adapted from The Surgeon General's Call to Action to Prevent Skin Cancer	

Results

The data obtained from this study met criteria for a valid assay and the controls performed as anticipated. **AC ExoCalm** at a 3.0% concentration was able to decrease the appearance of Red Area Counts on the face during the four-week treatment period and during the two-week regression period.

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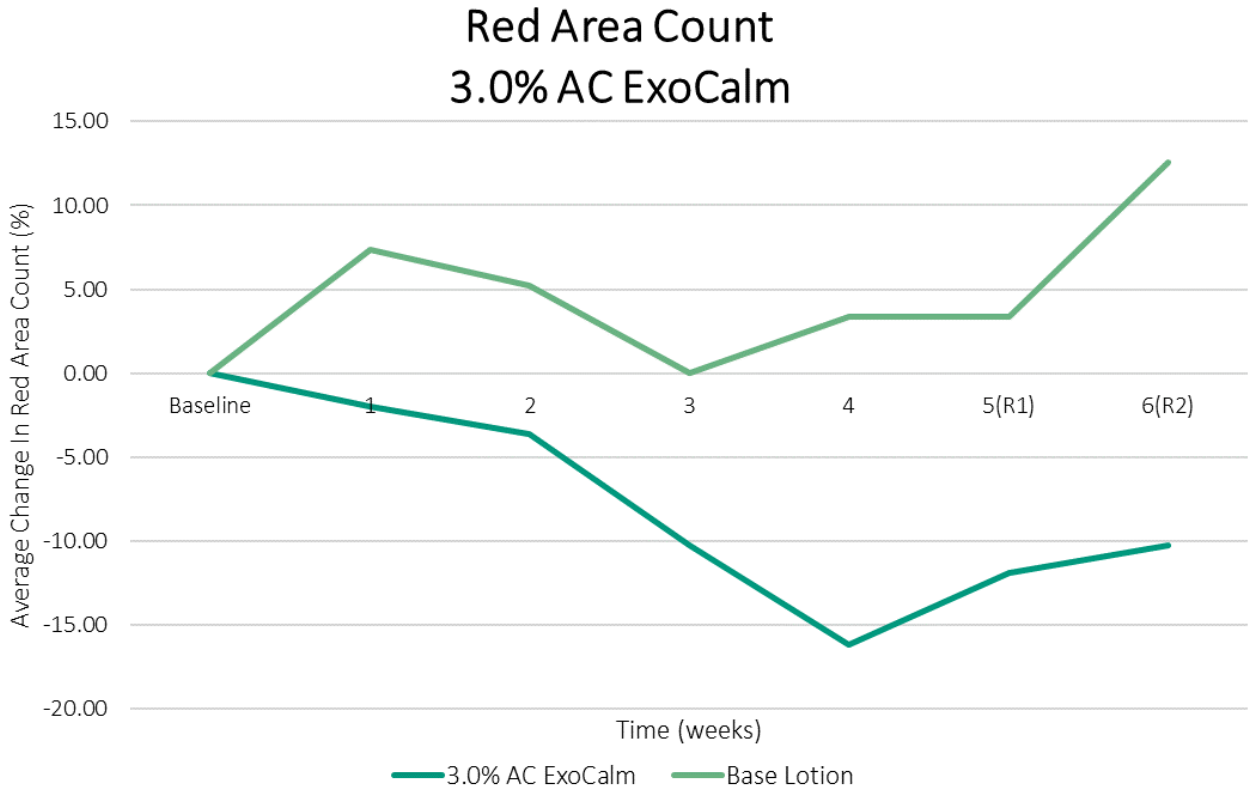

Figure 1. Average Percent Change of Red Areas from Baseline. R1 and R2 indicate regression weeks with no application.

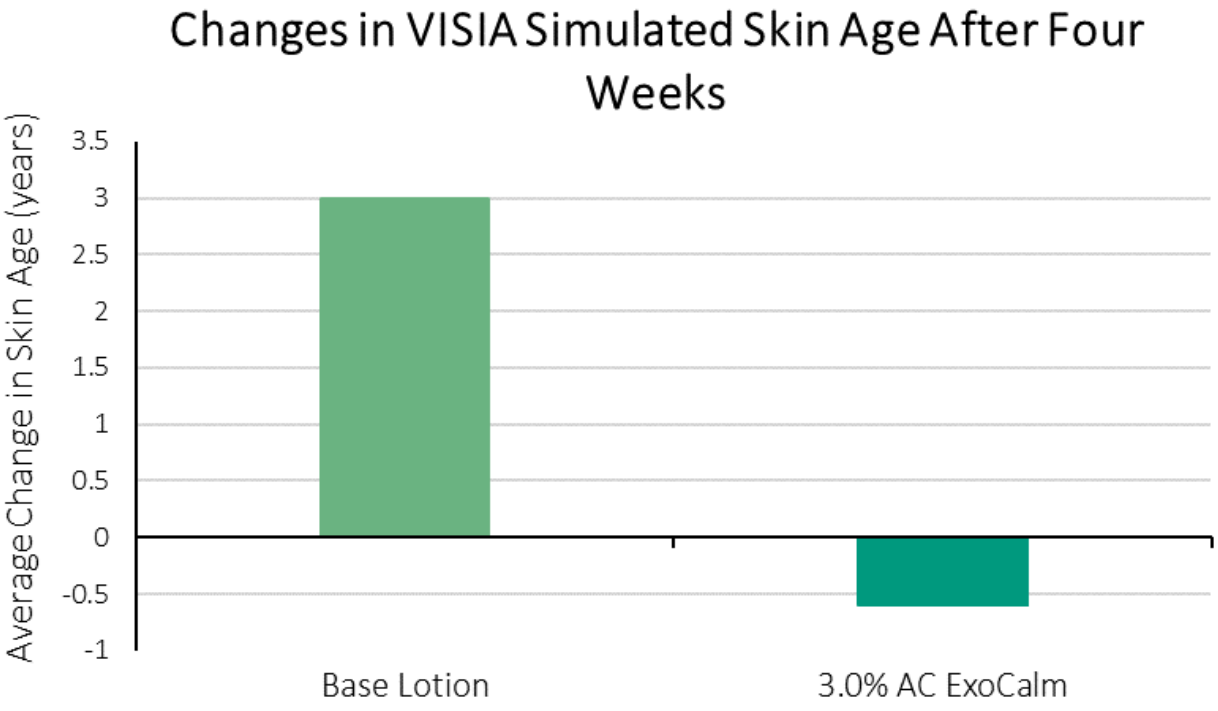

Figure 2. Changes in VISIA Simulated Skin Age of Participants After Four Weeks of 3.0% **AC ExoCalm** and Base Lotion Application.

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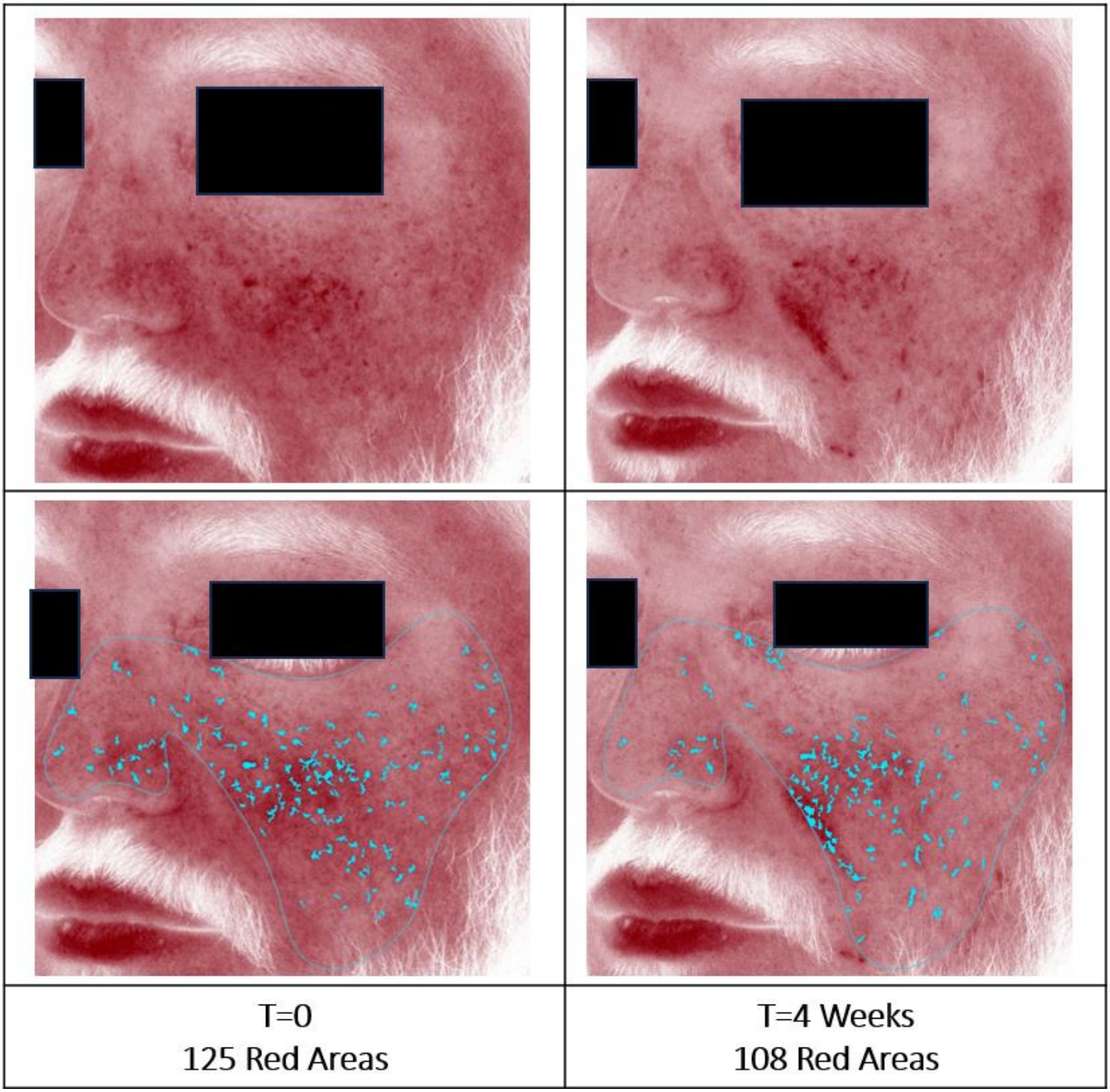

Figure 3. Images of Participant Treated with 3.0% **AC ExoCalm.** Natural photos (top) and VISIA Image Enhancement (bottom) Before and After Four weeks.

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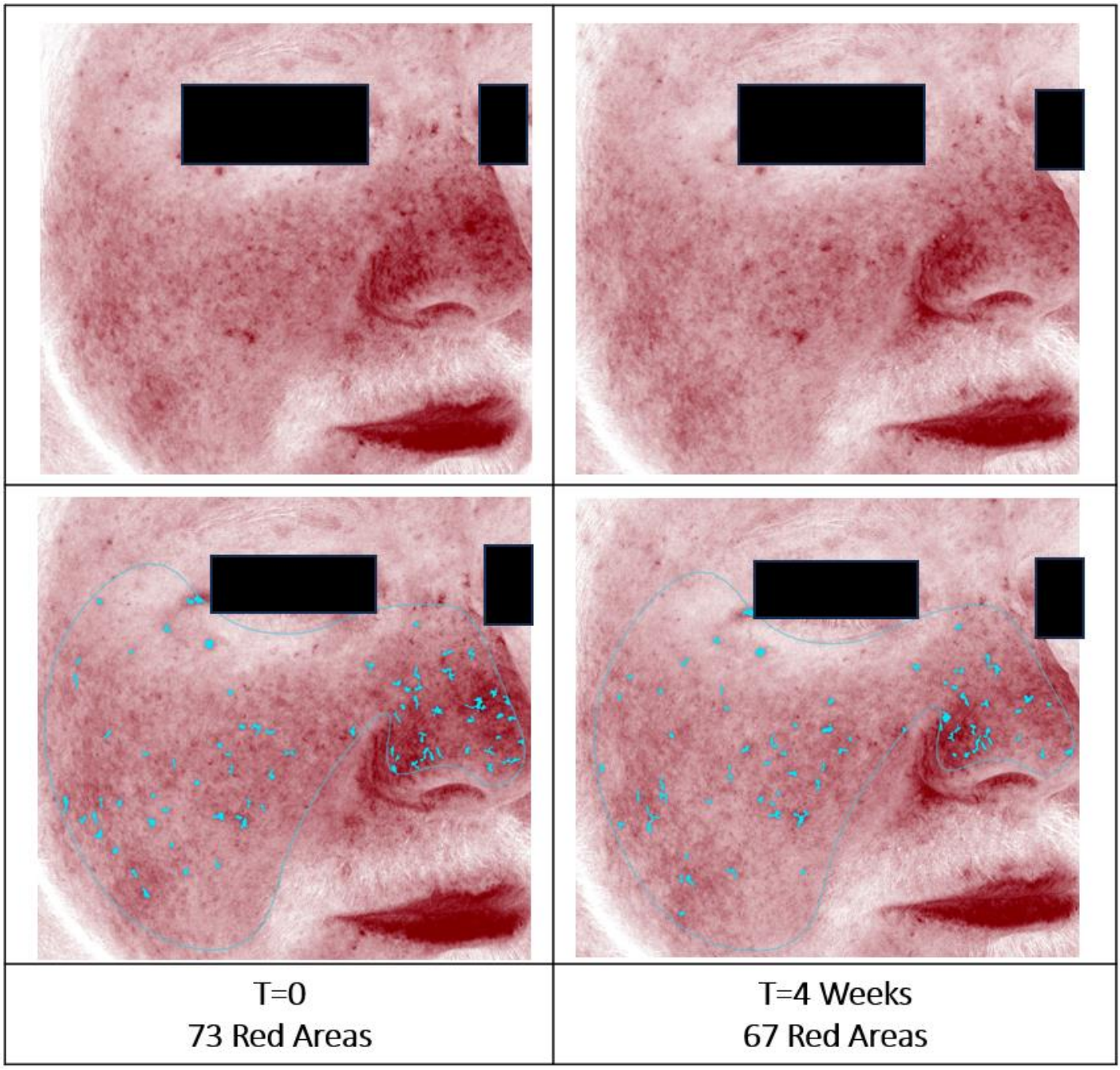

Figure 4. Images of Participant Treated with 3.0% **AC ExoCalm**. Natural photos (top) and VISIA Image Enhancement (bottom) Before and After Four weeks.

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Discussion

As evidenced in this four-week study, AC ExoCalm is capable of significantly reducing the appearance of Red Areas on the face. After four weeks, participants applying 3.0% AC ExoCalm demonstrated a 16% decrease in the overall number of Red Areas, compared to baseline (Figure 1). Conversely, base lotion application increased the total number of Red Areas by 3% in four weeks (Figure 1). Visually, participants experienced a decrease in the total number of Red Areas on the face after four weeks of applying 3.0% AC ExoCalm (Figures 3, 4). These results indicate that applying 3.0% AC ExoCalm for four weeks provides a reduction of Red Area appearance on the face resulting in a more youthful skin appearance.

After treatment ended, the reduction of Red Areas for participants applying 3.0% AC ExoCalm continued to outperform the base lotion alone. After two weeks of regression, the participants that applied the 3.0% AC ExoCalm demonstrated a 10% reduction in the total number of Red Areas, while the base lotion produced an increase of 13% (Figure 1). These results indicate that after treatment ended, participants applying 3.0% AC ExoCalm continued to see a reduction in the number of Red Areas on the face.

Additionally, the VISIA software analyzes each image and provides a Simulated Skin Age metric for each participant. After treatment ended, 3.0% AC ExoCalm decreased the VISIA Simulated Skin Age by 1 year, while the base lotion demonstrated an increase of 3 years (Figure 2). These results indicate that applying 3.0% AC ExoCalm for four weeks provides a reduction in VISIA Simulated Skin Age which reduced the visual impacts of normal aging.

Collectively, we provide evidence that applying AC ExoCalm for four weeks reduces simulated skin age, and the number of Red Areas present on the analyzed region. In conclusion, utilizing AC ExoCalm at the recommended use levels improves skin health and provides a more youthful appearance by reducing the visual consequences of bacterial development.

References

1. Sharma AN, Patel BC. Laser Fitzpatrick Skin Type Recommendations. [Updated 2022 Mar 9]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK557626/